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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,009	06/17/2003	Thomas Ferdinand A. Pijls	05032-00029	5778
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BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601			EXAMINER CHORBAJI, MONZER R	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/601,009

**Applicant(s)**

PIJLS, THOMAS FERDINAND A.

**Examiner**

MONZER R. CHORBAJI

**Art Unit**

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-27, 29-38, 40-43 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-27, 29-38, 40-43 and 47-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

**This non-final action is in response to the RCE/Amendment received on 09/05/2006**

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 25 recites the limitation "wherein after drying" in 14. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 25, 27, 29, 32-34, 37, 40 and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534), Den Hollander (U.S.P.N. 5,558,819), Scott et al (U.S.P.N. 3,925,560)

and further in view of ehow.com (How to Prepare Ready-to-Mix Powdered Baby Formula Internet printout).

Regarding claim 25, Pisecky discloses a method for spray drying heat sensitive liquids with steam (col.3, lines 47-56). An example of such a liquid is skimmed milk concentrate. Pisecky further teaches atomizing the liquid while admixing steam in a mixing chamber (col.6, lines 30-43) such that the liquid is pasteurized. Pisecky teaches a liquid to steam weight ratio between 1.6-10 (in col.10, Example 1, dividing 600 kg/h of product into 90kg/h of steam is equal to 7). In addition, Pisecky teaches drying the pasteurized liquid into powder form (see examples 1-4). However, Pisecky fails to teach the following: liquid solid content of at least 53%, steam pressure between 3-20 bar, the liquid residence time in the mixing chamber between 0.2-20 millisecond, primary particle size range and reconstituting the powder for infant consumption. Badertscher teaches that liquid has a solid content of at least 53% (page 5, left column) and that steam pressure between 3-20 bar (page 4, left column). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to increase steam pressure of Pisecky to that of Badertscher for guaranteeing optimal utilization of steam with remarkable stability conditions for sterilization (Badertscher, page 1, right column, lines 90-101) and to steam treat liquids with high solid contents as taught by the Badertscher reference (page 5, left column) so that wider range of different liquids with various solid contents can be steam treated as compared to only steam treat liquids with low solid contents.

Badertscher fails to teach the following: residence time range for products in the mixing chamber, primary particle size range and reconstituting the powder for infant consumption. Den Hollander recognizes that milk flavor must be retained after steam sterilization (col.7, lines 34-36) and further teaches that increasing milk's temperature to 150 degree Celsius in less than one second during its free fall in the down flow heater plant is sufficient time to destroy all microorganisms in milk (col.7, lines 25-31). This teaching infers that milk exposed to a temperature of 150 degree Celsius for less than one second is sufficiently sterilized. In addition, Den Hollander teaches against keeping the sterilized milk for additional time in the pressure chamber, as is conventional practice in this art. As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to minimize the implicit short time of liquid to steam exposure of the Pisecky's method (Pisecky, col.3, lines 47-56) to less than one second as evidenced by the teachings of Den Hollander in order to sterilize milk, yet retain its flavor and virtually prevent the occurrence of any denaturation (Den Hollander, col.7, lines 34-36) since such time modification is a matter of routine experimentation lacking any criticality.

Den Hollander fails to teach a size range for primary particles and reconstituting the powder for infant consumption. Scott teaches that after spray-drying the liquid product, the powder has a primary particle size of 10-60 micrometer (col.5, lines 4-5). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Pisecky's process by including a spray-drying step after steam sterilization so that milk is utilized as a vehicle for the administration of lipid-

soluble therapeutic substances as taught by Scott (col.1, lines 12-16) for the treatment of diseases.

Scott fails to teach reconstituting the powder for infant consumption. The ehow.com Internet printout discloses steps for dissolving powdered milk formula for infants (see steps 1-6). Clearly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Pisecky process of producing powdered milk by adding water mixing steps as taught by ehow.com so that preparing milk for infants is quickly accomplished (ehow.com Internet printout).

Regarding claims 29, 32, 34, 37, 40, 48 and 50-52, Pisecky discloses the following: milk (figure 1:16) inherently contains proteins or fats, the liquid to steam weight ratio between 1.6-10 (in col.10, Example 1, dividing 600 kg/h of product into 90kg/h of steam is equal to 7), the product milk is a stable emulsion since it is treated with steam over a very short time interval (figure 1:16, 17 and col.3, lines 47-56), pasteurized product leaving the mixing chamber flows into a drying chamber (col.6, lines 38-43) that would inherently agglomerate to produce a powder, spray dried milk is food for infants (col.6, lines 38-42), parallel flow openings for both of product and steam (figure 2:154, 156, 164 and 165), steam inflow is concentric around product inflow in the mixing chamber (figure 2:154, 156, 164, 165 and 104) and the steam is atomized in the mixing chamber (figure 1:4 and col.6, lines 34-37).

Regarding claim 27, Pisecky fails to disclose using steam with pressure values in the range of 5-15 bar. Badertscher teaches using steam with pressure values between 3-20 bar (page 4, left column). Therefore, it would have been obvious to one of ordinary

skill in the art at the time the invention was made to increase steam pressure of Pisecky to that of Badertscher so that optimal utilization of steam with remarkable stability conditions for sterilization (Badertscher, page 1, right column, lines 90-101) can be guaranteed.

Regarding claim 33, Pisecky fails to disclose heating the product to a temperature between 120-150 degree Celsius. Badertscher reference teaches (Example 4 on page 4) heating milk to a temperature from 70-150 degree Celsius. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to increase Pisecky's heat treatment temperature for milk as taught by the Badertscher reference so that effective sterilization of milk is accomplished.

Regarding claim 49, both Pisecky and Badertscher fail to teach placing distribution plate into the steam inflow openings. Den Hollander places distribution plates into steam inflow openings (figure 2:52). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place distribution plate into steam inflow opening of the spray drying atomizer wheel of Pisecky as taught by Den Hollander since distribution plates ensure steam uniform distribution (Den Hollander, col.3, lines 40-43).

6. Claims 26 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534), Den Hollander (U.S.P.N. 5,558,819), Scott et al (U.S.P.N. 3,925,560), ehow.com (How to Prepare Ready-to-Mix Powdered Baby Formula Internet printout) as applied to claim 25 and further in view of Rubens (EP 0 438 783).

Regarding claims 26 and 30-31, Pisecky, Badertscher, Den Hollander, Scott and ehow.com all fail to disclose specification values for the size of the mixing chamber and for the outlet opening. Rubens discloses a size for the mixing chamber (page 5, numbered lines 4-7) and for the outlet opening between 6.3 mm to 13 mm (page 5, numbered lines 32-35) and teaches that the value for the opening can be made smaller depending on other variables, i.e., temperature such that modifying the diameter of the outlet opening is a matter of choice of design that depends of the type of operational model used (page 5, numbered lines 33-35). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Pisecky's spray drying atomizer by modifying the sizes of the mixing chamber and the outlet openings as taught by Rubens since such modifications depend on the temperature and moisture content desired as well as the flow rates of the heating medium for heat treating liquid products (page 5, numbered lines 6-7 and lines 33-34).

7. Claims 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534), Den Hollander (U.S.P.N. 5,558,819), Scott et al (U.S.P.N. 3,925,560), ehow.com (How to Prepare Ready-to-Mix Powdered Baby Formula Internet printout) as applied to claim 25 and further in view of Arndt (U.S.P.N. 3,843,828).

Regarding claims 35-36, Pisecky, Badertscher, Den Hollander, Scott and ehow.com all fail to teach using a flash system. Arndt teaches that after treating the product with steam, passing the heated product to a flash system (col.5, lines 55-67). Thus, it would have been obvious to one having ordinary skill in the art at the time the



invention was made to modify Pisecky's process by including a flash system as taught by Arndt since a flashing system causes substantial cooling of the treated product resulting in shorter product heat exposure (col.5, lines 65-67 and col.6, lines 1-4).

8. Claims 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534), Den Hollander (U.S.P.N. 5,558,819), Scott et al (U.S.P.N. 3,925,560), ehow.com (How to Prepare Ready-to-Mix Powdered Baby Formula Internet printout) as applied to claims 37, 40 and further in view of Bond et al (U.S.P.N. 5,210,958).

Regarding claim 38, Pisecky, Badertscher, Den Hollander, Scott and ehow.com all fail to teach recycling the used steam. Bond teaches re-circulating used steam by increasing its temperature and returning it to the drying chamber (figure 1, 10, 18, 20, 18a and 22). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Pisecky's process by including a steam re-circulating means as taught by Bond in order to lower the overall energy consumption of the process (col.2, lines 44-49).

Regarding claim 41, Pisecky, Badertscher, Den Hollander, Scott and ehow.com all fail to teach drying liquid products with steam. Bond teaches steam drying (col.3, lines 15-22). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Pisecky's process by including a steam drying means as taught by Bond since steam drying can lead to a considerable capital cost savings and can also lead to a faster dry processing of products (col.2, lines 40-43).

9. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534), Den Hollander (U.S.P.N. 5,558,819), Scott et al (U.S.P.N. 3,925,560), ehow.com (How to Prepare Ready-to-Mix Powdered Baby Formula Internet printout), Bond et al (U.S.P.N. 5,210,958) as applied to claim 41 and further in view of Hovmand et al (U.S.P.N. 4,062,641).

Pisecky, Badertscher, Den Hollander, Scott, ehow.com and Bond all fail to teach re-circulating non-agglomerated particles to the drying chamber through spray nozzles. Hovmand teaches applying sequential heating steps by re-circulating the non-agglomerated particles (col.1, lines 47-53). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Pisecky's process by including re-circulating means for non-agglomerated particles as taught by Hovmand since a certain degree of agglomeration is desired for good dispersibility of food products in water and milk (col.6, lines 36-38).

10. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534), Den Hollander (U.S.P.N. 5,558,819), Scott et al (U.S.P.N. 3,925,560) and ehow.com (How to Prepare Ready-to-Mix Powdered Baby Formula Internet printout) as applied to 25 and further in view of Johnston (U.S.P.N. 2,401,077).

Pisecky, Badertscher, Den Hollander, Scott and ehow.com all fail to explicitly teach achieving microorganism decimal reduction of at least 2. Johnston teaches achieving decimal reduction of at least 2 (page 3, right column, lines 24-29). As a result,

it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Pisecky's process by including a decimal reduction step as taught by Johnston so that complete spores and bacterial destruction is accomplished (Johnston, page 3, right column, lines 26-28).

11. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534), Den Hollander (U.S.P.N. 5,558,819), Scott et al (U.S.P.N. 3,925,560) and ehow.com (How to Prepare Ready-to-Mix Powdered Baby Formula Internet printout) as applied to 25 and further in view of Bosund et al (U.S.P.N. 4,091,003).

Pisecky, Badertscher, Den Hollander, Scott and ehow.com all fail to explicitly disclose inherent features relating to the amount of solid product used in relation to the amount of steam. Bosund teaches that the protein solution to be dried is contacted in a packed column with steam where 0.1 to 1.0 kg of steam is used per kg of protein solution (col.4, lines 43-48). Instant claim 47 recites the equivalence inverse of Bosund teachings such that upon inversion, for example, the solid content is 5 kg protein/kg steam ( $1\text{ kg protein}/0.2\text{ steam} = 5\text{ kg protein/kg steam}$ ). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Pisecky's inherent mass content of product/steam to Bosund's solid range values since operating within this mass ratio range, deodorization and removal of all undesirable volatiles is achieved (col.4, lines 35-38).

***Response to Arguments***

Art Unit: 1744

12. Applicant's arguments with respect to claims 25-27, 29-38, 40-43 and 47-52 have been considered but are moot in view of the new ground(s) of rejection.


**Conclusion**

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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